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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,206	03/25/2005	Tcruo Aoyama	266057US0PCT	8829
22850	7590	09/11/2007		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
			EXAMINER BERMAN, SUSAN W	
			ART UNIT 1711	PAPER NUMBER
			NOTIFICATION DATE 09/11/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/529,206

Applicant(s)

AOYAMA ET AL.

Examiner

/Susan W. Berman/

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/05</u> . | 6) <input type="checkbox"/> Other: ____ |

Specification

The disclosure is objected to because of the following informalities: In Table 1, the product of (1) x (2) for example 2 should be 16,000 instead of 1,600.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 10: In line 6, it is not clear what is meant by “a hydrogenated thereof” or what “SEBS” or “SEPS” represent. In line 7, it is not clear what “ABS” represents. In line 8, it is not clear what “LLDPE”, “ULDPE” or “LDPE” represent. The use of parentheses around “with the proviso...weight” renders the claimed subject matter indefinite. The use of parenthesis in “(50% M: M2)” and in “(50% M: M1)” renders the claimed subject matter indefinite. It is not clear whether the material within the parenthesis is intended to define the claimed material or not. It is not clear what is meant by “50% stress”. What is the 50% a percentage of? What kind of stress is being measured? Does applicant intend to set forth tensile 50% stress as in Table 1? If so does “tensile” refer to tensile strength or tensile modulus or tensile breaking elongation? If so, what does the 50% refer to?

In claim 17, the units in parenthesis render the claim indefinite. It is suggested that applicant replace “voltage (kV)” with “voltage in kV”, for example.

In claim 26: In line 6, it is not clear what is meant by “a hydrogenated thereof” or what “SEBS” or “SEPS” represent. In line 7, it is not clear what “ABS” represents. In lines 7-8, it is not clear what “LLDPE”, “ULDPE” or “LDPE” represent. The use of parentheses around “with the proviso...weight” renders the claimed subject matter indefinite. The use of parenthesis in “(50% M: M2)” and in “(50% M: M1)” renders the claimed subject matter indefinite. It is not clear whether the material within the parenthesis is intended to define the claimed material or not.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-16 and 21-27 are rejected under 35 U.S.C. 102(e) as being anticipated by or alternatively under 35 U.S.C. 103(a) as being obvious over Ding et al (7,011,872, filed August 24,2001). Ding et al disclose a polymer blend of two 1,2 polybutadienes having different melting temperatures for fabricating medical products, such as tubes. The preferred polymer is syndiotactic 1,2-polybutadiene (column 3, line 52, to column 4, line 16. The blends are exposed

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to a sterilization dosage of about 25 kGys electron beam radiation (column 5, line 64, to column 6, line 18).

Since electron beam irradiation of syndiotactic 1,2-polybutadiene is disclosed for providing a medical product, as set forth in the instant claims, the articles disclose would be expected to exhibit the properties set forth in the instant claims. The prior art products would be expected to have a M2 to M1 ratio of 1.01 to 2.5 and to have steam sterilization resistance because the products are produced by method steps as set forth in the instant claims. For the same reason the properties set forth in the dependent claims would also be expected to be inherent to the products obtained by the instantly claimed process steps. The reason is that the method steps disclosed in the prior art would be expected to result in crosslinking that would provide the properties recited in the instant claims.

Once a reference teaching a product appearing to be substantially identical is made the basis of a rejection and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show an unobvious difference. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980). *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977). *In re Schreiber*, 128 F.3d 1473, 1478, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al (7,011,872, filed August 24, 2001) in view of Doheny, Jr. (5,063,005). See the discussion of the

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disclosure of Ding et al above. Ding et al teach exposure to a sterilization dosage of about 25 kGys electron beam radiation (column 5, line 64, to column 6, line 18). However, Ding et al do not mention the electron beam acceleration voltage.

Doheny, Jr. discloses electron beam irradiation of polyolefins to obtain a desired modulus. Doheny, Jr. teaches that needed radiation can be readily calculated by a skilled practitioner based upon dosage to effect the required crosslinking, such a line speed, kilovolts required to provide a penetrating potential and current (column 10, line 44, to column 11, line 2)

It would have been obvious to one skilled in the art at the time of the invention to determine the irradiations conditions, such as dosage and kilovolts, required to obtain a desired property or effect in the process disclosed by Ding et al, as taught by Doheny, Jr. Ding et al teach exposing the disclosed polymer blends to a sterilization dose of electron beam radiation of about 25 kGys and also teach that a gel content above 20% or preferably above 40% increases the mechanical strength of the medical pump tubing (column 5, line 64, to column 6, line 18). Doheny, Jr. teaches, in an analogous method for electron beam irradiation of polyolefins, that it is known in the art to determine the required dosage and energy to obtain a desired effect. One skilled in the art at the time of the invention would have been motivated by a reasonable expectation of obtaining desired sterilizing and crosslinking (gelling) effects in the polymer blends taught by Ding et al.

Double Patenting

Claims 10-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No.

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10/820878. Although the conflicting claims are not identical, they are not patentably distinct from each other because the medical member as defined in claims 1, 5, 9, 12, 15 and 18, for example, encompasses the article obtained by electron beam irradiation of syndiotactic 1,2-polybutadiene and having the properties set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Woo et al (6,187,400). Woo et al disclose medical tubing exposed to sterilization radiation of from about 15 to about 45 kGys to enhance its performance. Electron beam irradiation is said to improve elasticity and resiliency of the tubing (column 11, lines 13-42). The

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tubing comprises a first layer of ethylene homopolymers or copolymers, such as ethylene-vinyl acetate. The tubing material can be blended with from 5 to 95% of a polyolefin (column 6, lines 28-53). A radiation sensitive additive, such as syndiotactic polybutadiene, can be added in amounts from 0.01 to 20% (column 6, line 54, to column 7, line 30).

Nakamura et al (4,465,487) disclose a container for medical use that can withstand high pressure steam sterilization. The main body of the container is formed by electron beam crosslinking an ethylene-vinyl acetate copolymer. There is no mention of syndiotactic 1,2-polybutadiene.

Hsu et al (6,956,093) disclose preparation of syndiotactic polybutadiene rubber compositions. Tires comprising the rubber compositions are taught.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SB
8/21/2007

/Susan W Berman/
Primary Examiner
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